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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/314,497	05/19/99	SCHINDLY	B	MED-2-1012

IM22/0214

THOMAS E KOCOVSKY JR
FAY SHARPE BEALL FAGAN MINNICH & MCKEE
1100 SUPERIOR AVENUE
7TH FLOOR
CLEVELAND OH 44114

EXAMINER	
CHORBAJI,M	
ART UNIT	**PAPER NUMBER**
1744	4

DATE MAILED: 02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/314,497	SCHINDLY ET AL.	
	Examiner	Art Unit	
	MONZER R CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1, 3, 15-16, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 3-4, applicant uses the phrase "selectively releasing". It is not clear how or by what mechanism the anti-microbial decontaminate is released. Clarification is needed to understand the meaning of claim1.

Claim 3, lines 5 and lines 7-8, applicant uses the phrase "selectively water transmissive". It is not clear what is meant by this phrase. Clarification is needed to understand the meaning of claim 3.

Claim 15, line 4, applicant uses the phrase "sufficient period of time". It is not clear how much time is sufficient to effect decontamination. Is there a time range that would result in a sufficient decontamination? Clarification is needed to understand the meaning of claim 15. The same question also applies to claim 16, lines 4-5. Clarification is needed to understand the meaning of claim 16.

Claim 21, line 7, applicant uses the phrase "for a period of time". It is not clear how much is a period of time. Is there a time range that would better explain such a phrase? Clarification is needed to understand the meaning of claim 21.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minerovic et al (U.S.P.N. 5,997,814) in view of Malchesky et al (U.S.P.N. 5,518,927).

Minerovic et al teaches of a package, col.2, line 12, which can be used in a single application, for holding a powdered composition, col.2, line 12, which forms a solution of an anti-microbial decontaminate when mixed with water, col.2, lines 13-14, and for selectively releasing the composition, col.3, lines 60-62, the package comprising: a porous portion, col.5, lines 63-67, and col.6, lines 33-35; first compartment for receiving a first component of the composition, second compartment for receiving a second component of the composition, col.2, lines 27-30, the porous portion, first compartment, and second compartment configured for forming a fluid flow path for the decontaminate solution through the package, col.6, lines 52-60, and col.10, lines 12-27; cartridge or package further includes: outer, first cup, figure 3 (50), including a first peripheral wall, figure 3 (52), with an opening at an end, figure 3 (60), the first peripheral wall being at least selectively water transmissive, col.8, lines 8-17, inner second cup, figure 3 (70), including a second peripheral wall, figure 3 (72), second peripheral wall

being at least selectively water transmissive, col.8, lines 24-27, the first and second cups being configured such that the second peripheral wall abuts, figure 4 (74), and is connected to the first cup, figure 4 (54), adjacent the end of the first peripheral wall, figure 4 (52), top cover, figure 4 (94), covering the openings in the first and second cups, such that the first compartment, figure 4 (88), is defined in the first cup, figure 4 (50), and the second compartment, figure 4 (not labeled), is defined in the second cup, figure 3 (70); first peripheral wall includes a region which is formed from a first material, col.9, lines 54-56; first cup peripheral wall includes a side and a base, figure 3 (50, 52, and 60), and wherein the base is detachable from the side, figure 4 (58); second peripheral wall, figure 4 (72), includes a region which is formed from a second material, col.9, lines 56-57, which is impermeable to the first and second components but is permeable to water and to solutions containing dissolved components, col.8, lines 57-62, second peripheral wall defines a hemisphere and is formed from the second material, figure 4 (72); top cover defines the porous portion, col.9, lines 34-35; porous portion is formed from non-woven polypropylene web, col.6, lines 24-27; decontaminate includes peracetic acid, col.7, line 10, first component includes acetylsalicylic acid and the second component includes sodium perborate, col.10, lines 1-3; well, figure 2 (16), for receiving the package of claim 1, source of water connected with the well, col.5, lines 9-16, for mixing with the powdered composition to form the antimicrobial solution, a microbial decontamination chamber, figure 2 (C), connected with the well for receiving the anti-microbial

solution, the well the porous region and the chamber forming a re-circulating fluid flow path for the decontaminate solution, col.4, lines 66-67, and col.5, lines 1-31; package for releasing an antimicrobial composition into a flowing liquid, comprising: side wall, figure 3 (52), having a first opening, figure 3 (56), at a first end, and a second opening, figure 3 (60), at a second end such that the liquid flows through the first opening into the package and out through the second opening, layer of porous material, figure 4 (94), spanning one of the first and second openings such that the liquid flows through the porous material layer, figure 2 (C, 16, 28, 24, 14, and 12), an antimicrobial source is disposed within the package, figure 4 (88), for releasing the antimicrobial composition into the flowing liquid, figure 2 (C, 16, 28, 24, 14, and 12), to form an antimicrobial solution. Minerovic et al further teaches of a method including all the limitations mentioned above, columns 10-12. In addition, Minerovic et al teaches of using measured amounts of the reagents to form the required concentration of the sterliant to effect sterilization, col.2, lines 1-3, and also uses the word "metering" a preselected amounts of both reagents, col.3, lines 24-45, but Minerovic et al does not explicitly mention of a certain range of concentration of the sterilant. Furthermore; Minerovic et al teaches of using a heater, figure 2 (30), to maintain the circulating sterilant at a certain temperature, but does not explicitly mention of a certain range of temperature.

Minerovic et al does not teach of using an indicator, which exhibits a detectable change on exposure to the decontaminant in the solution.

Malchesky et al teaches of an instrument and a method in the art of sterilizing medical equipment, col.1, lines 6-27, comprising the following: an indicator, col.6, lines 17-18, on the porous portion, col.5, lines 61-62, which exhibits a detectable change, col.2, lines 20-24, on exposure to the decontaminant in the solution, col.3, lines 24-26; indicator includes an oxidizable species, col.2, lines 22-24, on prolonged contact with the solution, col.3, line 61, and col.4, line 3; indicator is specific for the decontaminat, col.3, lines 23-30, peracetic acid is used in the art of sterilization, col.3, lines 26-32, and is used in the preferred embodiment of this prior art along with crystal violet so that a good correlation between the decontaminant and the indicator can be established without the interference of other factors, such as pH, indicator is impregnated into the porous portion, abstract, lines 1-3, in the form of an ink, col.6, lines 37-42, and col.6, lines 13-18; sufficient concentration, col.3, line 64, for a sufficient period of time, col.3, line 61; an indicator provides a detectable color change when peracetic acid is at a concentration of about 900 PPM or above, col.3, lines 62-65, for a preselected period of time; wherein the decontaminant is peracetic acid, col.3, line 63, and the indicator is crystal violet, col.3, line 52; an indicator on the porous material layer which changes color in response to contact with the antimicrobial solution, a degree of color change varying in accordance with a concentration of an antimircobial agent and duration, col.5, lines 61-67, and col.6, lines 1-7; examining the indicator for the detectable change, col.6, lines 29-36.

Thus, it would have been obvious and one having ordinary skill in the art would have been motivated to combine the teaching of Minerovic et al for an apparatus and a method of using a package for holding a powdered composition which forms a solution of an anti-microbial decontaminant used the sterilization and disinfection arts with another art-known in the sterilization and disinfection for using an indicator which exhibits a detectable color change as taught by Malchesky et al for the known and expected results of providing an accurate and quick system for maintaining an adequate levels of the sterilant in a decontamination cycle.

Conclusion

6. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Siegel et al (U.S.P.N. 5,209,909), Siegel et al (U.S.P.N. 5,662,866), Schneider et al (U.S.P.N. 5,037,623), Kralovic et al (U.S.P.N. 4,731,222), Antonoplos et al (U.S.P.N. 5,942,438), Watanabe et al (U.S.P.N. 5,489,281), Watanabe et al (U.S.P.N. 5,417,676), McNeil et al (U.S.P.N. 5,403,549), Tratnyek (U.S.P.N. 4,407,960), and Hof et al (U.S.P.N. 4,362,645) teach other similar apparatuses and methods.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-7719 for After Final communications.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Robert J. Warden, Sr.

ROBERT J. WARDEN, SR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
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